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ATLANTIS® Anterior Cervical Plate System

AUG 15 2008

510(k) Summary

July 2008

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Chris McKee**
Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** ATLANTIS® Anterior Cervical Plate System

III. **Classification Name(s):** Metallic Bone Fixation Appliance; Class: II; Product Code(s): KWQ; and Regulation No.: 888.3060

IV. **Legally Marketed Devices:** ATLANTIS® Anterior Cervical Plate System (K970806)

V. **Description:** The ATLANTIS® Anterior Cervical Plate System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion.

The ATLANTIS® Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

The ATLANTIS® Anterior Cervical Plate System implant components are made from titanium alloy, with certain plates having subcomponents manufactured from a superelastic alloy (Nitinol-NiTi). Stainless steel and titanium implant components must not be used together in a construct.

VI. **Indications for Use**: Properly used, this system is intended for anterior interbody screw/plate fixation from C2 to T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

VII. **Substantial Equivalence**: Documentation, including a risk analysis and prior mechanical testing, was provided which demonstrated the subject plates to be substantially equivalent to predicate

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ATLANTIS® Anterior Cervical Plate System plates previously cleared in K970806, K021461 and K063100 and the C-Tek® MaxAn™ Anterior Cervical Plate System cleared in K080646.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Medtronic Sofamor Danek
% Mr. Chris Mckee
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K081038
Trade/Device Name: ATLANTIS® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis.
Regulatory Class: Class II
Product Code: KWQ
Dated: July 24, 2008
Received: July 29, 2008

Dear Mr. McKee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

July 2008

510(k) Number (if known): K081038

Device Name: ATLANTIS® Anterior Cervical Plate System

Indications for Use

Properly used, this system is intended for anterior interbody screw/plate fixation from C2 to T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehrig for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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